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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/536,860

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Hana Golding

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EDWARDS ANGELL PALMER & DODGE LLP  
(CLIENT REFERENCE NO. 47992)

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EXAMINER

CHEN, STACY BROWN

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/536,860	<b>Applicant(s)</b> GOLDING, HANA	
	<b>Examiner</b> Stacy B. Chen	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-129 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-129 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, Applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Group I, claims 1-21; the special technical feature is a method of detecting a candidate agent that modulates invasion of a cell by an invasin. Claims 1, 12, 13, 17, 18 and 21 link the following groups. Applicant must elect one embodiment from each of the members of the group. This is not a species election.
  - **Type of modulation activity of candidate agent** (claims 2 and 3): Elect an agent that increases invasion or an agent that decreases invasion.
  - **Invasin** (claims 4-11): Elect either viruses or bacteria. If viruses are elected, Applicant must further elect either enveloped or non-enveloped viruses. Additionally, a specific virus must be elected if enveloped viruses are elected (one of herpesvirus, orthomyxovirus, retrovirus, influenza, vaccinia, or smallpox).
  - **Candidate agent** (claim 14): Elect compound, antibody, or enzyme.
  - **Association of candidate agent** (claims 15, 16, 19 and 20): Elect an agent that associates with the invasin, or an agent that associated with the cell. If agents that associate with the cell are elected, Applicant must further elect one cell receptor from the list in claim 20.

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- Group II, claim 22; the special technical feature is an agent that modulates invasion of a cell by an invasion.
- Group III, claims 23-45; the special technical feature is a method of determining whether a specimen contains an antibody that decreases invasion of a cell by an invasin. Claims 23-30 and 42-45 link the following groups. Applicant must elect one embodiment from each of the members of the group. This is not a species election.
  - **Antibody binding** (claims 31 and 32): Elect an antibody that binds to the invasin or an antibody that binds to the cell. If antibodies that bind the cell are elected, Applicant must further elect one cell receptor from the list in claim 34.
  - **Invasin** (claims 35-41): Elect either viruses or bacteria. If viruses are elected, Applicant must further elect either enveloped or non-enveloped viruses. Additionally, a specific virus must be elected if enveloped viruses are elected (one of herpesvirus, orthomyxovirus, retrovirus, influenza, vaccinia, or smallpox).
- Group IV, claims 46-58; the special technical feature is a method of determining whether a human has been exposed to smallpox or has antibodies to smallpox.
- Group V, claims 59-69; the special technical feature is a method of determining whether a specimen contains an antibody that binds to a preselected antigen.
- Group VI, claims 70-83; the special technical feature is a method of determining whether an antibody binds to a receptor used by an invasin to invade a cell. Claims 70 and 76-83 link the following groups. Applicant must elect one embodiment from each of the members of the group. This is not a species election.

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- **Invasin** (claims 71-75): Elect either viruses or bacteria. If viruses are elected, Applicant must further elect either enveloped or non-enveloped viruses.
- Group VII, claims 84-92; the special technical feature is a method of determining whether a candidate agent modulates antibody-mediated infection of a cell. Claims 84 and 90-92 link the following groups. Applicant must elect one embodiment from each of the members of the group. This is not a species election.
  - **Invasin** (claims 85-89): Elect either viruses or bacteria. If viruses are elected, Applicant must further elect either enveloped or non-enveloped viruses.
  - Group VIII, claims 93-103; the special technical feature is a method of determining whether an antibody mediates transport of an invasion across a cell monolayer. Claims 93 and 101-103 link the following groups. Applicant must elect one embodiment from each of the members of the group. This is not a species election.
    - **Type of antibody transport activity** (claims 94 and 95): Elect an antibody that increases transport of the invasin or decreases transport of the invasin.
    - **Invasin** (claims 96-100): Elect either viruses or bacteria. If viruses are elected, Applicant must further elect either enveloped or non-enveloped viruses. If bacteria are elected, Applicant must further elect one bacterium from claim 100.
- Group IX, claims 104-122; the special technical feature is a method of assaying invasin load in an organism. Claims 104, 107 and 116-120 link the following groups. Applicant must elect one embodiment from each of the members of the group. This is not a species election.
  - **Organism** (claims 105, 106, 108 and 109): Elect an avian, a mammal or a reptile.

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- **Invasin** (claims 110-115): Elect either viruses or bacteria. If viruses are elected, Applicant must further elect either enveloped or non-enveloped viruses. Additionally, a specific virus must be elected if enveloped viruses are elected (one of herpesvirus, orthomyxovirus, retrovirus, influenza or vaccinia).
- **Administration of candidate agent** (claims 121 and 122): Elect administration of the agent prior to infection with the invasin, or post-infection with the invasin.
- Group X, claims 123-129; the special technical feature is a kit comprising an invasin and cell that the invasin can invade.

2. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Although there is does not appear to be any particular unifying technical feature, the prior art does disclose an assay that comprises mixing cells with HIV-1-GFP reporter viruses in neutralizing antibody assays and antiviral agent testing (Auewarakul *et al.*, *Asian Pacific Journal of Allergy and Immunology*, 2001, 19(2):139-144, see abstract and page 143, second column, "DISCUSSION"). Therefore, the asserted special technical feature is anticipated by the prior art. Since there is no special technical feature linking the claimed subject matter, the claims lack unity of invention.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. The

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election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Should Applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

5. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B Chen/  
Primary Examiner, Art Unit 1648